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Degenhard Marx

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Alexandria, VA 22314

EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

01/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,821	<b>Applicant(s)</b> MARX ET AL.	
	<b>Examiner</b> SAMIRA JEAN-LOUIS	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-16, and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

This Office Action is in response to the amendment submitted on 09/23/08. Claims 1, 3-16, and 18-20 are currently pending in the application, with claims 2 and 17 having being cancelled. Accordingly, claims 1, 3-16, and 18-20 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the rejection of claims 1-16 and 18-20 under 35 U.S.C. §112, first paragraph has been fully considered. Given that applicant has deleted the term "solvates" and amended the claims, such rejection is now moot. Consequently, the rejection of claims 1-16 and 18-20 under 35 U.S.C. §112, first paragraph is hereby withdrawn.

Applicant's arguments with regard to Magee et al. who teach isotonic compositions has been fully considered but is not found persuasive. While Magee et al. teach that their invention can be utilized as ophthalmic compositions wherein the pharmaceutical compositions **may** be formulated as micronized suspension, pH adjusted sterile saline solution (see pg. 104, paragraph 708), the invention does not

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exclude non-isotonic compositions as Magee clearly teaches addition of osmotic pressure controlling agents which clearly suggests that Magee et al. envisaged other types of solutions. The Examiner further points out that while ophthalmic solutions are conventionally formulated in isotonic solutions, hypotonic solutions can also be made. In fact, Chastaing et al. teach that ophthalmic solutions can comprise hypotonic solutions (see Chastaing et al., see abstract; col. 2, lines 20-24 and 40-52, and col. 3, lines 10-12). Chastaing et al. importantly teach that conventional ophthalmic solutions are usually prepared as isotonic solutions; however, Chastaing et al. teach his present invention as hypotonic solutions with a freezing point of  $-0.28^{\circ}\text{C}$  to  $-0.4^{\circ}\text{C}$  and wherein the hypotonicity is between 150-215 mOsm/kg (see col. 5, lines 11-26). Moreover, Chastaing et al. demonstrated that the hypotonic solutions of the invention were more bioavailable as compared to isotonic solutions further providing a motivation as to why one skilled in the art would be motivated to utilize a hypotonic ophthalmic composition. Consequently, given the disclosure of Magee et al. about the addition of osmotic pressure controlling agents, Magee's lack of teaching of specific osmotic pressure numerical values, and Magee's teachings that suggest pharmaceutical compositions of various tonicities, the Examiner asserts that Magee et al. necessarily envisaged compositions of various tonicities. Accordingly, the Examiner contends that the rejection of the aforementioned claims was indeed proper and is therefore maintained.

Applicant's argument with respect to Calatayud et al. who do not remedy the deficiencies of Magee et al. since Calatayud et al. do not teach any particular osmotic

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pressure has been fully considered but is not found persuasive. Again, the Examiner reiterates the fact that Magee et al. do not exclude non-isotonic solutions as Magee et al. clearly stated that the pharmaceutical compositions of the invention may be isotonic suggesting that non-isotonic are envisaged as well. Furthermore, Calatayud was provided to demonstrate that the epimer of ciclesonide provides intense pharmacological activity, high anti-inflammatory activity, high glucocorticoid activity, and high therapeutic index with no systemic side effects. Accordingly, the Examiner contends that one of ordinary skill in the art would have found it obvious and be motivated to utilize the epimer of ciclesonide since Calatayud teaches particular epimers of ciclesonide with high therapeutic activity. Thus, the Examiner contends that the rejection of the aforementioned claims was indeed proper and is therefore maintained.

Applicant's argument with respect to Szelenyl who does not teach hypotonic solutions but rather isotonic solutions has again been fully considered but is not found persuasive. Szelenyl teaches suitable agents that **can** be added to his compositions but not necessarily **have to be** included (see col. 4, lines 6-14 and 29-33). Like Magee et al., Szelenyl teaches various formulations and compositions in the form of an eye drop (see col. 3, lines 58-59). As previously mentioned, Szelenyl does not teach any specific osmotic pressure numerical values and in view of Szelenyl's addition of tonicity agents, one of ordinary skill in the art would readily envisaged that Magee et al. necessarily envisaged non-isotonic compositions as well. Moreover, as previously

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discussed, Chastaing et al. demonstrated that hypotonic solutions may be formulated as hypotonic solutions wherein such solutions are more bioavailable than their isotonic counterparts further providing the rationale as to why one of ordinary skill in the art would formulate such eye drops as hypotonic solutions. As for the rejection of claim 19 over Szelenyi in view of Calatayud, the Examiner contends that Calatayud was provided to demonstrate that epimers of ciclesonide provide high therapeutic activity and thus one of ordinary skill in the art would have found it obvious and be motivated to utilize such epimer given its therapeutic effect. Accordingly, the Examiner contends that a *prima facie* case has indeed been established and thus the rejections of claims 1-16, 18, and 20 and claim were indeed proper and are therefore maintained.

For the aforementioned reasons, the rejections of record remain proper and are therefore maintained. However, in view of applicant's amendment, the following 112, second paragraph and modified 103 (a) Final rejections are being made.

***Claim Rejections - 35 USC § 112 (Lack of Antecedent Basis)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-14 recite the limitation "for application to the mucosa according to claim 1 and/or claim 11" in claims 3-14 and the limitation "said water-insoluble and/or water-

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low soluble substances” in claim 8. There is insufficient antecedent basis for these limitations in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 3-16, 18, and 20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Magee et al. (U.S. 2002/0111495 A1, previously cited).**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Magee et al. teach the use of selective PDE4 inhibitors for improved therapeutic treatment of a number of inflammatory, respiratory and allergic diseases including chronic rhinitis (i.e. allergic rhinitis; instant claim 18; see pg. 1, paragraph 0006 and pg. 81, paragraphs 0467-0472). Magee et al. further teach that the present compounds can be used together in combination with one or more therapeutic agents including antihistaminic H2 receptor antagonists such as azelastine (instant claims 15-16), the steroid ciclesonide and with pharmaceutically carriers (instant claim 1; see pg. 34, paragraph 0218 and pg. 92, paragraph 0570-0571). The compositions of Magee et al. can be administered to humans (instant claim 20; see pg. 76, paragraph 0423). Magee et al. also teach the route of administration that can critically affect bioavailability, solubility of the active agents and rapid absorption (see pg. 100, paragraph 0677). By carriers, Magee et al. teach addition of acceptable diluents, adjuvants, vehicles viscosity modifiers and other agents known to the artisan for providing favorable properties to the final pharmaceutical composition including water as a solvent, salts such as sodium chloride for isotonic properties (i.e. osmotic pressure-controlling agent; instant claim 7), cellulose-based substances such as sodium carboxymethylcellulose (i.e. water soluble polymer; instant claims 8-9 and 12), polyethylene glycol as a wetting agent, polyethylene polyoxypropylene block polymer as a surfactant (instant claim 13), emollients, humectants such as glycerin (instant claim 13), surfactants and sugars such as glucose (instant claim 7; see pg. 100-102, paragraphs 0677, 0688 and 0697-0698).



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Magee et al. further teach that the composition for intranasal application (i.e. nasal mucosa, instant claim 14, see pg. 104, paragraph 0708).

Magee et al. does not specifically teach a composition with a particular osmotic pressure or a composition containing microcrystalline cellulose as solid particles in an aqueous medium.

However, Magee et al. do teach the inclusion of water-low soluble substance such as cellulose derivatives which encompasses all substances containing cellulose including microcrystalline cellulose which are solid particles before addition to the pharmaceutical composition. Moreover, Magee et al. teach the use of viscosity modifiers and given that microcrystalline cellulose is a well-known viscosity modifier, one of ordinary skill would readily add such compound as solid particles as to obtain the desired product with the desired osmotic pressure. Additionally, Magee et al. teach the addition of osmotic pressure controlling agents including glucose and sodium chloride. Consequently, these agents would necessarily affect the osmotic pressure of the composition due to their tonicity properties. Thus, to acquire the desired osmotic pressure for enhancing the bioavailability of the active ingredients as suggested by Magee et al., one of ordinary skill would be motivated to vary the concentration of the osmotic pressure controlling agents in a particular form in the composition.

Moreover, applicant is reminded that a prior art reference may “render obvious” without disclosing a feature of the claimed invention, as long as that missing

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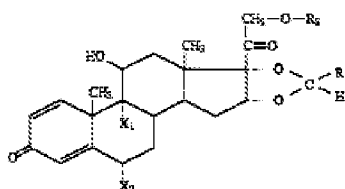
characteristic is necessarily present, or inherent, in the anticipating reference. Please see *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). Other precedents of the court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. Please see, e.g., *In re Cruciferous Sprout Litig*, 301 F.3d 1343, 1351 (Fed. Cir. 2002); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999) (Where the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results". In the instant case, the unappreciated osmotic pressure of Magee's composition does not require recognition by Magee et al.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the method of Magee et al. to treat allergic rhinitis while varying the concentration of the osmotic pressure controlling agents since the motivation of Magee et al. was to provide a composition with enhanced bioavailability and enhanced rate of absorption. Given that Magee et al. teach a method of treating allergic rhinitis with PDE4 inhibitors, azelastine and ciclesonide with additional excipients, one of ordinary skill would have been motivated to utilize the method of Magee et al. and vary the concentration of water soluble agents and osmotic pressure controlling agents with the reasonable expectation of providing a composition that is efficacious in treating allergic rhinitis and a composition that is readily absorbed.

**Claim 19 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Magee et al. (U.S. 2002/0111495 A1, previously cited) as applied to claims 1, 3-16, 18, and 20 and in further view of Calatayud et al. (U.S. 5,482,934, previously cited).**

The Magee reference is as discussed above and incorporated by reference herein. However, Magee does not specifically teach the mixture of the “R” and “S” epimers in a mixing ratio into the composition.

Calatayud et al. teach compounds of the general formula



with X<sub>1</sub> and X<sub>2</sub> corresponding to H and R<sub>1</sub> is a phenyl group and R<sub>2</sub> represents radicals such as C=OCH(CH<sub>3</sub>)CH<sub>3</sub> in the form of an R epimer, S epimer or mixture of the R and S epimers (i.e. ciclesonide) as drugs and/or therapeutic agents (see abstract and col. 3, lines 1-61). Calatayud et al. further teach that these compounds possess intense pharmacological activity with no or minimal systemic effects (see col. 2 lines 21-23, col. 15, lines 10-11 and col. 16, lines 27-30). Calatayud et al. also teach synthesis of the mixture of ciclesonide with both the R and S epimers in a ratio of 45/55 of R/S (see col. 11, lines 21-61). Importantly, Calatayud et al. teaches that the mixture of R and S epimers of ciclesonide possess high anti-inflammatory activity, high

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glucocorticoid activity and high therapeutic index (see col. 17-18, table 2-3 compounds 7-9).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute the mixture of epimers of ciclesonide into the composition of Magee et al. to treat allergic rhinitis while varying the concentration of the osmotic pressure controlling agents since Calatayud et al. teach that the mixture of epimers possesses intense glucocorticoid activity with minimal systemic effects. Given that Magee et al. teach a method of treating allergic rhinitis with PDE4 inhibitors, azelastine and ciclesonide with additional excipients, and Calatayud et al. teach mixtures of epimers of ciclesonide with high glucocorticoid activity and minimal systemic effects, one of ordinary skill would have been motivated to substitute the mixture of epimers of ciclesonide into the composition of Magee et al. with the reasonable expectation of providing a composition that is efficacious in treating allergic rhinitis and a composition that is readily absorbed with no systemic effects.

**Claims 1, 3-16, 18, and 20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Szelenyi et al. (WO 01/22955, previously cited) in view of Schmidt et al. (J. Clin. Pharmacol. 1999, Vol. 39, pgs. 1062-1069, previously cited).**

WO 01/22955 is the PCT counterpart to U.S. 7,022,687 B1. WO 01/22955 A1 is prior art under U.S.C. 102 (b) as a result of its April 05, 2001 publication date. U.S. 7,022,687 B1 is prior art under U.S.C. 102 (e). Because WO 01/22955 and U.S.

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7,022,687 B1 appear to have identical disclosures, the U.S. patent is being used as a translation of WO 01/22955 PCT. While any reference hereinafter to column and line numbers will be based upon the U.S. patent disclosure, such reference should be interpreted as referring to the corresponding disclosure of the aforementioned PCT counterpart.

Szelenyl et al. teach the combination of a soft steroid such as loteprednol and at least one antihistamine, such as azelastine and/or levocabastine for the local treatment of allergies and airway disorders including allergic rhinitis (see abstract and col. 6, claims 1-2, 4-5, 8; instant claims 1, 15-16, and 18). The administration can be intranasal (instant claim 14; see col. 1, line 66, and col. 2, line 53) and the composition can further include solvents such as water, preservatives, stabilizers such as water soluble polymers such as sodium carboxymethyl-cellulose or mixtures of microcrystalline cellulose and sodium carboxymethylcellulose known as Avicel RC (instant claims 2, 8-9, 11-12), isotonicizing agents such as sodium chloride or glucose (i.e. osmotic pressure controlling agents; instant claim 7), and suitable wetting agents (instant claim 13; col. 4, lines 5-14, 29-33, and 45-67).

Szelenyl et al. do not particularly teach a composition containing ciclesonide. Similarly, Szelenyl et al. do not teach a composition with a specific osmotic pressure value or a composition containing microcrystalline cellulose as solid particles in an aqueous medium.

While Szelenyl et al. do not teach particular osmotic pressures, he does teach the addition of water soluble substances along with isotonicizing agents which are solid particles in nature in the composition which would necessarily affect the osmotic pressure. Thus, it would have been within the purview of the skilled artisan to experiment with varying concentrations of the aforementioned compounds and various forms of the aforementioned products as to obtain the desired product with the desired osmotic pressure.

Schmidt et al. teach the use of the soft steroid, ciclesonide, as an effective steroid in the treatment of allergic rhinitis without producing local or systemic effects (see abstract). Schmidt et al. further teaches that ciclesonide has an "R" epimer with a higher binding affinity than the "S" epimer to the glucocorticoid receptor (see pg. 1063, left col. paragraph 1). This compound can be administered intranasally (see pg. 1063, right col. paragraph 1) was found to be highly effective in the treatment of allergic rhinitis and led to a rapid alleviation of symptoms without producing systemic side effects (see pg. 1069, left col., last paragraph).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute the ciclesonide of Schmidt et al. for the loteprednol of Szelenyl et al. to treat allergic rhinitis since Schmidt et al. teach that ciclesonide possesses low systemic effects. Moreover, as a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very

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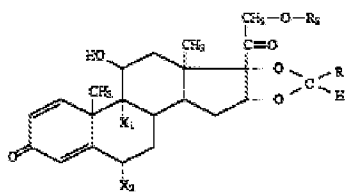
same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

Given that Szelenyl et al. teach a composition containing a soft steroid and antihistamines for treating allergic rhinitis with additional excipients, and Schmidt et al. teach that ciclesonide is effective in treating allergic rhinitis without producing local or systemic effects, one of ordinary skill would have been motivated to substitute the ciclesonide of Schmidt et al. for the loteprednol of Szelenyl et al. with the reasonable expectation of providing a composition that is efficacious in treating allergic rhinitis and a composition with minimal side effects.

**Claim 19 is rejected under 35 U.S.C. 103 (a) as being unpatentable over unpatentable over Szelenyl et al. (WO 01/22955, previously cited) in view of Schmidt et al. (J. Clin. Pharmacol. 1999, Vol. 39, pgs. 1062-1069, previously cited) as applied to claims 1, 3-16, 18, and 20 and in further view of Calatayud et al. (U.S. 5,482,934, previously cited).**

The Szelenyl et al. reference is as discussed above and incorporated by reference herein. However, Szelenyl et al. do not particularly teach the mixture of the “R” and “S” epimers in a mixing ratio into the composition.

Calatayud et al. teach compounds of the general formula



with X1 and X2 corresponding to H and R1 is a phenyl group and R2 represents radicals such as  $\text{C}=\text{OCH}(\text{CH}_3)\text{CH}_3$  in the form of an R epimer, S epimer or mixture of the R and S epimers (i.e. ciclesonide) as drugs and/or therapeutic agents (see abstract and col. 3, lines 1-61). Calatayud et al. further teach that these compounds possess intense pharmacological activity with no or minimal systemic effects (see col. 2 lines 21-23, col. 15, lines 10-11 and col. 16, lines 27-30). Calatayud et al. also teach synthesis of the mixture of ciclesonide with both the R and S epimers in a ratio of 45/55 of R/S (see col. 11, lines 21-61). Importantly, Calatayud et al. teach that the mixture of R and S epimers of ciclesonide possess high anti-inflammatory activity, high glucocorticoid activity and high therapeutic index (see col. 17-18, table 2-3 compounds 7-9).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute the mixture of epimers of ciclesonide into the composition of Szelenyl et al. to treat allergic rhinitis since Calatayud et al. teach that the mixture of epimers possesses intense glucocorticoid activity with minimal systemic effects. Given that Szelenyl et al. teach a composition of treating allergic rhinitis with azelastine or levocabastine and a soft steroid along with additional excipients, and Schmidt et al. teach the use of ciclesonide for treating allergic rhinitis with low systemic effects, and



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Calatayud et al. teach mixtures of epimers of ciclesonide with high glucocorticoid activity and minimal systemic effects, one of ordinary skill would have been motivated to substitute the mixture of epimers of ciclesonide for the "R" epimer into the composition of Szelenyi et al. with the reasonable expectation of providing a composition that is efficacious in treating allergic rhinitis and a composition that possesses no systemic effects.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L./

Examiner, Art Unit 1617

01/05/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617